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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/586,054	06/02/2000	Peter D. Hill	98-37	5574

7590 04/09/2003

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EXAMINER

EREZO, DARWIN P

ART UNIT	PAPER NUMBER
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3761

DATE MAILED: 04/09/2003

13

Please find below and/or attached an Office communication concerning this application or proceeding.

N.K.

Office Action Summary	Application No. 09/586,054	Applicant(s) HILL ET AL.	
	Examiner Darwin P. Erez	Art Unit 3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

ACE (1/17/03)

- 1) ☒ Responsive to communication(s) filed on 31 October 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-32 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-32 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 1/17/03 has been entered.

Response to Arguments

2. Applicant's arguments filed 1/17/03 have been fully considered but they are not persuasive. The amended claims now recite the limitation "wherein the average tidal volume is determined irrespective of a period of time during which the plurality of inspiratory phases occur". Upon further consideration, it is not understood by the examiner as to how it is possible to determine an "average tidal volume" irrespective of a period of time since calculating an average of tidal volumes inherently occurs over a period of time, i.e., the number of tidal volume for each inspiratory phase occurs over a period of time. For example, determining an average tidal volume over five inspiratory phases occurs over a period of time those five inspiratory phases actually occur.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1-32 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

5. Claims 1, 7, 8, 13, 19, 23, 27 and 28 recite the limitation "wherein the average tidal volume is determined irrespective of a period of time during which the plurality of inspiratory phases occur" which renders the claims vague and indefinite because it is unclear as to how an average tidal volume is calculated independent of a period of time. See comments in "Response to Arguments" section.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting

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directly or indirectly from an international application filed before November 29, 2000.

Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

7. Claims 1-4, 13, 14, 16-25, 27 and 30-32 are rejected under 35 U.S.C. 102(e) as being anticipated by US 6,041,780 to Richard et al.

8. **As to Claim 1**, Richard teaches a method of adjusting a volume of a fluid supplied to a patient, the method comprising the steps of:

supplying a plurality of volumes of fluid to a patient during a like plurality of inspiratory phases of a respiratory cycle of such a patient, each volume of fluid being supplied at inspiratory positive airway pressure during a corresponding inspiratory phase (col. 4, lines 35-42);

determining, for each inspiratory phase, a tidal volume of fluid received by such a patient (col. 4, lines 43-45);

determining an average tidal volume of fluid received by such a patient from the volumes of fluid received by such a patient during the plurality of inspiratory phases (col. 4, line 65 – col. 5, line 5);

comparing the average tidal volume to a predetermined target tidal volume; and adjusting the inspiratory positive airway pressure based on the comparison (col. 4, line 28 – col. 5, line 17).

9. **As to Claim 2**, Richard teaches a method wherein estimating, for each inspiratory phase, a volume of fluid leaked from a breathing gas supply system that supplies such a patient with the plurality of volumes of fluid, and combining, for each

inspiratory, the volume of fluid leaked and the volume of fluid supplied to such a patient to obtain the tidal volume of fluid received by such a patient (col. 4, lines 45-50).

10. **As to Claims 3 and 4**, Richard teaches a method of adjusting the IPAP level so as to gradually conform an actual tidal volume to a target tidal volume. Therefore, this method would inherently perform the steps recited in the claim.

11. **As to Claim 13**, Richard teaches an apparatus for supplying fluid to a patient , the apparatus comprising

a pressure generator system **14** adapted to provide a flow of fluid at one of a variable pressure and a variable flow;

a patient circuit **18** operatively coupled to the pressure generating system to deliver the flow of fluid to a patient;

an interface device **16** operatively coupled to the patient circuit to communicate the flow of fluid to an airway of a patient;

at least one sensor **26** operatively coupled to the interface device to detect a parameter indicative of a volume of fluid delivered to such a patient; and

a controller **24** operatively coupled to the sensor and the pressure generating system, wherein the controller determines a tidal volume of fluid received by the patient for each inspiratory phase, determines an average tidal volume of fluid over a plurality of inspiratory phases; compares the average tidal volume of fluid to a predetermined target tidal volume, and causes the pressure generating system to adjust one a pressure and a rate of flow of the fluid based on the comparison (col. 4, line 28 – col. 5, line 17).

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12. **As to Claim 14**, Richard teaches a controller that causes the pressure generating system to increase the pressure when an average tidal volume is less than a predetermined target tidal volume; decrease the pressure when the average tidal volume is greater than the predetermined target tidal volume; and maintain the pressure when the average tidal volume is within the target tidal volume (col. 4, lines 17-28).
13. **As to Claim 16**, Richard teaches an apparatus wherein the pressure generating system includes a fluid source that outputs the flow of fluid and a pressure regulator (col. 3, line 66 – col. 4, line 4).
14. **As to Claim 17**, Richard teaches an apparatus wherein the at least one sensor includes a flow sensor **26** and a pressure sensor **28** and wherein the controller estimates fluid leakage (col. 4, line 45-48).
15. **As to Claim 18**, it is inherent for the operation of the device of Richard to perform the recited limitation as disclosed in col. 4, lines 43-57.
16. **As to Claim 19**, Richard teaches an apparatus for supplying fluid to a patient comprising a pressure generating means **14**, delivering means **18**, interfacing means **16**, sensing means **26**, and processing means **24** (col. 4, line 28 – col. 5, line 17).
17. **As to Claim 20**, Richard teaches a processing means that performs the recited function in col. 4, lines 42-57.
18. **As to Claim 21**, Richard teaches a controller that causes the pressure generating system to increase the pressure when an average tidal volume is less than a predetermined target tidal volume; decrease the pressure when the average tidal

volume is greater than the predetermined target tidal volume; and maintain the pressure when the average tidal volume is within the target tidal volume (col. 4, lines 17-28).

19. **As to Claim 22**, it is inherent for the operation of the device of Richard to perform the recited limitation as disclosed in col. 4, lines 43-57.

20. **As to Claim 23**, Richard teaches an apparatus comprising supplying means **14**, tidal volume determining means **26**, average tidal volume determining means (through processor **24**), comparing means and adjusting means (col. 4, line 28 – col. 5, line 17).

21. **As to Claim 24**, Richard teaches an tidal volume determining means including leak estimating means (col. 4, lines 42-57).

22. **As to Claim 25**, Richard teaches a controller that causes the pressure generating system to increase the pressure when an average volume is less than a predetermined target volume; decrease the pressure when the average tidal volume is greater than the predetermined target tidal volume; and maintain the pressure when the average tidal volume is within the target tidal volume (col. 4, lines 17-28).

23. **As to Claim 27**, Richard teaches an apparatus comprising supplying means **14**, determining means, averaging means, comparing means, and adjusting means (through processor **24**; col. 4, line 28 – col. 5, line 17).

24. **As to Claims 30 and 31**, Richard teaches an apparatus of adjusting the IPAP level so as to gradually conform an actual tidal volume to a target tidal volume.

Therefore, the device would inherently perform the recited limitation.

25. **As to Claim 32**, Richard teaches an inspiratory volume determining means including leak estimating means (col. 4, lines 42-57).

Claim Rejections - 35 USC § 103

26. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

27. Claims 5, 7-12, 15, 26, 28 and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Richard et al.

28. **As to Claim 5**, Richard teaches all the limitations of the claim except for the predetermined pressure of approximately 0.1 cm H₂O. However, Richard does teach thus use of using a predetermined pressure of approximately 1 cm H₂O. Therefore, it would have been obvious to one of ordinary skill in the art to use any predetermined pressure depending on the intended therapy and the size of the patient. Furthermore, the Applicant has not disclosed that the specific predetermined pressure solves any stated problems or is for any particular purpose.

29. **As to Claims 7-9**, Richard teaches a method of supplying fluid to a patient, comprising: supplying a first volume of fluid to a patient at a first inspiratory positive airway pressure; determining, for the first volume of fluid supplied to such a patient, a first tidal volume of fluid received by such a patient; supplying a second volume of fluid to such a patient at the first inspiratory positive airway pressure; determining for the second tidal volume of fluid supplied to such a patient, a second volume of fluid received by such patient; determining, based on the first and the second tidal volumes of fluid received by such a patient, a first average tidal volume of fluid received by such

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patient. Though Richard does not specifically teach comparing the first average tidal volume to a predetermined target tidal volume and adjusting the first inspiratory positive airway pressure to a second inspiratory positive airway pressure based on the comparison in the comparing step, it would have been an obvious step because Richard teaches the step of comparing the average volume after a certain time frame and adjusting the inspiratory positive airway pressure based on the comparison. Therefore, the method step of Richard is capable of performing the recited step, including a third volume or a fourth volume. Furthermore, the inspiratory airway pressures can be the same depending on the patient.

30. **As to Claims 10 and 11**, it is inherent in the method steps of Richard to have the second inspiratory positive airway pressure be greater than the first inspiratory positive airway pressure if the average volume is lower than the target volume or to have the inspiratory positive airway pressure be the same as the first inspiratory positive airway pressure if the average volume is within the target volume.

31. **As to Claim 12**, Richard teaches a method of performing leak estimation (col. 4, lines 45-48).

32. **As to Claim 15**, Richard teaches a controller that is fully capable of performing the recited limitation.

33. **As to Claim 26**, Richard teaches a processor that is fully capable of performing the recited limitation.

34. **As to Claims 28 and 29**, Richard teaches an apparatus that compares the average tidal volume after a certain time frame and adjusting the inspiratory positive

airway pressure based on the comparison. Therefore, the apparatus of Richard is fully capable of performing the recited function, including a third volume or a fourth volume. Furthermore, the inspiratory airway pressures can be the same depending on the patient.

Allowable Subject Matter

35. Claim 6 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Darwin P. Erez who telephone number is (703) 605-0420. The examiner can normally be reached on M-F (8:30-5:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Weilun Lo can be reached on (703) 308-1957. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9302 for regular communications and (703) 872-9303 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

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March 31, 2003


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